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Committee on the Environment, Public Health and Food Safety

2012/0278(COD)

30.5.2013

AMENDMENTS 77 - 191

Draft report
Sandrine Bélier
(PE508.195v02-00)

Access to Genetic Resources and the Fair and Equitable Sharing of Benefits
Arising from their Utilization in the Union

Proposal for a regulation
(COM(2012)0576 – C7-0322/2012 – 2012/0278(COD))

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EN

United in diversity

EN

Amendment 77
Anna Rosbach

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) The European Union recognises the interdependence of all countries with regard to genetic resources for food and agriculture, as well as their special nature and importance for achieving food security worldwide and for the sustainable development of agriculture in the context of poverty alleviation and climate change and acknowledging the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard.

Or. en

Justification

The relevance for food security of genetic resources for food and agriculture and their relevance for adapting to climate change should be noted in the Regulation.

Amendment 78
Anna Rosbach

Proposal for a regulation
Recital 2 b (new)

Text proposed by the Commission

Amendment

(2b) It is recognised practice to exchange all plant genetic resources for food and agriculture for research, breeding and training purposes under the terms and condition of the Standard Material

Transfer Agreement (SMTA) established under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) as determined in the Memorandum of Understanding for the establishment of the European Genebank Integrated System (AEGIS); in accordance with Article 4.3 of the Protocol, it is acknowledged that such a practice is supportive of, and does not run counter to, the objectives of the Convention and the Protocol.

Or. en

Amendment 79
Anna Rosbach

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission

Amendment

(3a) Competence and responsibility for the practical implementation of measures to safeguard indigenous and local communities in access and benefit sharing arrangements would remain with Member States and their courts.

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 80
Pavel Poc, Cristina Gutiérrez-Cortines

Proposal for a regulation
Recital 6

Text proposed by the Commission

(6) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Nagoya Protocol significantly expands the general rules of the Convention on access and benefit-sharing for the *use* of genetic resources and traditional knowledge associated with genetic resources.

Amendment

(6) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Nagoya Protocol significantly expands the general rules of the Convention on access and ***monetary and non-monetary*** benefit-sharing for the ***utilisation and any subsequent commercialisation*** of genetic resources and traditional knowledge associated with genetic resources.

Or. en

Justification

Non-monetary benefits should at least be mentioned in the Recital Paragraphs, as they are part of the Nagoya Protocol (Article 5). The addition of 'any' before 'subsequent commercialization' serves to indicate that commercialization is not an inevitable concomitant to utilization (and indeed is much less common than non-commercial utilization).

Amendment 81
Anna Rosbach

Proposal for a regulation
Recital 6

Text proposed by the Commission

(6) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Nagoya Protocol ***significantly expands*** the general rules of

Amendment

(6) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Nagoya Protocol ***further elaborates*** the general rules of the

the Convention on access and benefit-sharing for the use of genetic resources and traditional knowledge associated with genetic resources.

Convention on access and benefit-sharing for the use of genetic resources and traditional knowledge associated with genetic resources.

Or. en

Justification

As also specified in Article 3 of the Nagoya Protocol, the protocol implements Article 15 of the Convention on Biological Diversity (CBD) and cannot therefore expand the general rules contained in this Article of the CBD.

Amendment 82

Christa Klaß, Herbert Dorfmann, Elisabeth Jeggle, Elisabeth Köstinger

Proposal for a regulation

Recital 6

Text proposed by the Commission

(6) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Nagoya Protocol ***significantly expands*** the general rules of the Convention on access and benefit-sharing for the use of genetic resources and traditional knowledge associated with genetic resources.

Amendment

(6) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Nagoya Protocol ***sets out in greater detail*** the general rules of the Convention on access and benefit-sharing for the use of genetic resources and traditional knowledge associated with genetic resources.

Or. de

Amendment 83

Maria do Céu Patrão Neves

Proposal for a regulation

Recital 6

Text proposed by the Commission

(6) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Nagoya Protocol **significantly expands** the general rules of the Convention on access and benefit-sharing for the use of genetic resources and traditional knowledge associated with genetic resources.

Amendment

(6) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Nagoya Protocol **further details** the general rules of the Convention on access and benefit-sharing for the use of genetic resources and traditional knowledge associated with genetic resources.

Or. en

Amendment 84

Pavel Poc, Cristina Gutiérrez-Cortines

Proposal for a regulation

Recital 6

Text proposed by the Commission

(6) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Nagoya Protocol **significantly expands** the general rules of the Convention on access and benefit-sharing for the use of genetic resources and traditional knowledge associated with genetic resources.

Amendment

(6) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Nagoya Protocol **further details** the general rules of the Convention on access and benefit-sharing for the use of genetic resources and traditional knowledge associated with genetic resources.

Or. en

Justification

As also specified in Article 3 of the Nagoya Protocol, the protocol implements Article 15 of the CBD and cannot therefore expand the general rules contained in that Article.

Amendment 85
Gerben-Jan Gerbrandy

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission

Amendment

(8a) Unauthorised acquisition of genetic resources, or unauthorised utilisation or subsequent commercialisation of products based on such resources or associated traditional knowledge should be prohibited.

Or. en

Justification

The due diligence the Commission puts in place needs to be accompanied by a general prohibition on the illegal use of genetic resources. This reverses the burden of proof, as is already the case for illegal timber (Regulation (EU) No. 995/2010) and for IUU fishing, facilitating the judicial process and enforcement by the respective competent national authorities.

Amendment 86
Gerben-Jan Gerbrandy

Proposal for a regulation
Recital 8 b (new)

Text proposed by the Commission

Amendment

(8b) Unauthorised acquisition of genetic resources, or unauthorised utilisation or subsequent commercialisation of products based on such resources or associated traditional knowledge are made subject to criminal sanctions in accordance with

Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law¹.

¹ *OJ L 328, 6.12.2008, p. 28*

Or. en

Justification

The prohibition needs to be accompanied by sufficiently deterrent sanctions. The Commission proposal leaves this entirely at the discretion of Member States; it does not foresee criminal sanctions but only fines, suspension of activity and confiscation of the genetic resources.

Amendment 87

Christa Klaß, Herbert Dorfmann, Elisabeth Jeggle, Elisabeth Köstinger

Proposal for a regulation

Recital 11

Text proposed by the Commission

(11) It is important to define, in accordance with the Nagoya Protocol, that use of genetic resources refers to research and development on the genetic or biochemical composition of ***samples of genetic material, which includes research and development on isolated compounds extracted from genetic material that was accessed in a Party to the Nagoya Protocol.***

Amendment

(11) It is important to define, in accordance with the Nagoya Protocol that the use of genetic resources refers to research and development on the genetic or biochemical composition of genetic ***resources.***

Or. de

Amendment 88

Maria do Céu Patrão Neves

Proposal for a regulation

Recital 11

Text proposed by the Commission

Amendment

(11) It is important to define, in accordance with the Nagoya Protocol, that use of genetic resources refers to research and development on the genetic or biochemical composition of ***samples of genetic material, which includes research and development on isolated compounds extracted from genetic material that was accessed in a Party to the Nagoya Protocol.***

(11) It is important to define, in accordance with the Nagoya Protocol, that ***the*** use of genetic resources refers to research and development on the genetic or biochemical composition of genetic ***resources.***

Or. en

Amendment 89

Pavel Poc

Proposal for a regulation

Recital 11

Text proposed by the Commission

Amendment

(11) It is important to define, in accordance with the Nagoya Protocol, that ***use*** of genetic resources refers to research and development on the genetic or biochemical composition of ***samples of genetic material, which includes research and development on isolated compounds extracted from genetic material that was accessed in a Party to the Nagoya Protocol.***

(11) It is important to define, in accordance with the Nagoya Protocol, that ***utilisation*** of genetic resources refers to research and development on the genetic or biochemical composition of genetic ***resources.***

Or. en

Justification

The unclear definition of ‘use/utilization’ as given in Article 3(6) opens up a dangerous spectrum of interpretations. The definition of ‘utilization’ from the Nagoya Protocol shall be employed and consistent use of the term needs to be ensured. This recital should reflect the definition of “use of genetic resources” under Article 3 of the Regulation in order to avoid misleading interpretation and to be in line with the definition of “utilization” provided under Article 2 of the Nagoya Protocol.

Amendment 90
Cristina Gutiérrez-Cortines

Proposal for a regulation
Recital 11

Text proposed by the Commission

(11) It is important to define, in accordance with the Nagoya Protocol, that **use** of genetic resources refers to research and development on the genetic or biochemical composition of **samples of genetic material, which includes research and development on isolated compounds extracted from genetic material that was accessed in a Party to the Nagoya Protocol.**

Amendment

(11) It is important to define, in accordance with the Nagoya Protocol, that **utilization** of genetic resources refers to research and development on the genetic or biochemical composition of genetic **resources.**

Or. en

Amendment 91
Anna Rosbach

Proposal for a regulation
Recital 13

Text proposed by the Commission

(13) There is currently no internationally agreed definition on ‘traditional knowledge associated with genetic resources’ or on ‘holding’ such knowledge by an indigenous and local community. International definitions of those terms and concepts are being negotiated in the Intergovernmental Committee of the World Intellectual Property Organization. Therefore, in order to ensure flexibility and legal certainty for providers and users, this Regulation should make reference to traditional knowledge associated with genetic resources as described in benefit-

Amendment

deleted

sharing agreements.

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 92

Anna Rosbach

Proposal for a regulation

Recital 14

Text proposed by the Commission

(14) With a view to ensuring an effective implementation of the Nagoya Protocol, all users of genetic resources *and traditional knowledge associated with such resources* should have to exercise due diligence to ascertain that the genetic resources *and associated traditional knowledge* used were accessed in accordance with applicable legal requirements and to ensure that, where relevant, benefits are shared. However, given the diversity of users within the Union it is not appropriate to oblige all users to take the same measures for exercising due diligence. Therefore, only minimum features of due diligence measures should be set out. The specific choices taken by users on the tools and measures applied for exercising due diligence should be supported through the recognition of best practices as well as complementary measures in support of sectoral codes of conduct, model contractual clauses, and guidelines with a view to increasing legal certainty and reducing costs. The obligation on users to keep information relevant for access and benefit-sharing should be limited in time, consistent with the time-span for an

Amendment

(14) With a view to ensuring an effective implementation of the Nagoya Protocol, all users of genetic resources should have to exercise due diligence to ascertain that the genetic resources used were accessed in accordance with applicable legal requirements and to ensure that, where relevant, benefits are shared. However, given the diversity of users within the Union it is not appropriate to oblige all users to take the same measures for exercising due diligence. Therefore, only minimum features of due diligence measures should be set out. The specific choices taken by users on the tools and measures applied for exercising due diligence should be supported through the recognition of best practices as well as complementary measures in support of sectoral codes of conduct, model contractual clauses, and guidelines with a view to increasing legal certainty and reducing costs. The obligation on users to keep information relevant for access and benefit-sharing should be limited in time, consistent with the time-span for an eventual innovation.

eventual innovation.

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 93

Christa Klaß, Herbert Dorfmann, Elisabeth Jeggle, Elisabeth Köstinger

Proposal for a regulation

Recital 14

Text proposed by the Commission

(14) With a view to ensuring an effective implementation of the Nagoya Protocol, all users of genetic resources and traditional knowledge associated with such resources should have to exercise due diligence to ascertain that the genetic resources and associated traditional knowledge used were accessed in accordance with applicable legal requirements and to ensure that, where relevant, benefits are shared. However, given the diversity of users within the Union it is not appropriate to oblige all users to take the same measures for exercising due diligence. ***Therefore, only minimum features of due diligence measures should be set out. The specific choices taken by users on the tools and measures applied for exercising due diligence should be supported through the recognition of best practices as well as complementary measures in support of sectoral codes of conduct, model contractual clauses, and guidelines with a view to increasing legal certainty and reducing costs.*** The obligation on users to keep information relevant for access and benefit-sharing should be limited in time, consistent with the time-span for an

Amendment

(14) With a view to ensuring an effective implementation of the Nagoya Protocol, all users of genetic resources and traditional knowledge associated with such resources should have to exercise due diligence to ascertain that the genetic resources and associated traditional knowledge used were accessed in accordance with applicable legal requirements and to ensure that, where relevant, benefits are shared. However, given the diversity of users within the Union it is not appropriate to oblige all users to take the same measures for exercising due diligence. ***This applies in particular to subsequent users, to whom the due diligence obligation should apply only if they access and use genetic resources in the same way as the initial user.*** The obligation on users to keep information relevant for access and benefit-sharing should be limited in time, consistent with the time-span for an eventual innovation.

eventual innovation.

Or. de

Amendment 94
Esther de Lange

Proposal for a regulation
Recital 14

Text proposed by the Commission

(14) With a view to ensuring an effective implementation of the Nagoya Protocol, all users of genetic resources and traditional knowledge associated with such resources should have to exercise due diligence to ascertain that the genetic resources and associated traditional knowledge used were accessed in accordance with applicable legal requirements and to ensure that, where relevant, benefits are shared. However, given the diversity of users within the Union it is not appropriate to oblige all users to take the same measures for exercising due diligence. Therefore, only minimum features of due diligence measures should be set out. ***The specific choices taken by users on the tools and measures applied for exercising due diligence should be supported through the recognition of best practices as well as complementary measures in support of sectoral codes of conduct, model contractual clauses, and guidelines with a view to increasing legal certainty and reducing costs.*** The obligation on users to keep information relevant for access and benefit-sharing should be limited in time, consistent with the time-span for an eventual innovation.

Amendment

(14) With a view to ensuring an effective implementation of the Nagoya Protocol, all users of genetic resources and traditional knowledge associated with such resources should have to exercise due diligence to ascertain that the genetic resources and associated traditional knowledge used were accessed in accordance with applicable legal requirements and to ensure that, where relevant, benefits are shared. However, given the diversity of users within the Union it is not appropriate to oblige all users to take the same measures for exercising due diligence. Therefore, only minimum features of due diligence measures should be set out. ***Particularly in the case of subsequent users, for whom the due diligence obligation should only apply in the case such users access and use genetic resources in the form as originally accessed by the initial user.*** The obligation on users to keep information relevant for access and benefit-sharing should be limited in time, consistent with the time-span for an eventual innovation.

Or. en

Amendment 95
Maria do Céu Patrão Neves

Proposal for a regulation
Recital 16

Text proposed by the Commission

(16) Best practices developed by users should play an important role in identifying due diligence measures that are particularly suitable for achieving compliance with the system of implementation of the Nagoya Protocol with high legal certainty and at low costs. Users should be enabled to build on existing access and benefit-sharing codes of conduct developed for the academic sector and different industries. Associations of users should be able to request that the Commission determines whether a specific combination of procedures, tools or mechanisms overseen by an association may be recognised as best practice. Competent authorities of the Member States should consider that the implementation of a recognised best practice by a user reduces that user's risk of non-compliance and justifies a reduction in compliance checks. The same should apply to best practices adopted by the collective of the Parties to the Nagoya Protocol.

Amendment

(16) ***The specific choices taken by users on the tools and measures applied for exercising due diligence should be supported through the recognition of best practices.*** Best practices developed by users should play an important role in identifying due diligence measures that are particularly suitable for achieving compliance with the system of implementation of the Nagoya Protocol with high legal certainty and at low costs, ***as well as complementary measures in support of sectoral codes of conduct and model-contractual clauses.*** Users should be enabled to build on existing access and benefit-sharing codes of conduct developed for the academic sector and different industries. Associations of users should be able to request that the Commission determines whether a specific combination of procedures, tools or mechanisms overseen by an association may be recognised as best practice. Competent authorities of the Member States should consider that the implementation of a recognised best practice by a user reduces that user's risk of non-compliance and justifies a reduction in compliance checks. The same should apply to best practices adopted by the collective of the Parties to the Nagoya Protocol.

Or. en

Amendment 96
Pavel Poc

Proposal for a regulation
Recital 17

Text proposed by the Commission

(17) Users should declare at identified points in the chain of activities that **constitute use that** they have exercised due diligence. Suitable points for such declarations are the **receiving of public research funds, when** a market approval for a product developed on the basis of genetic resources is requested or at the time of commercialisation where a market approval is not required. Notably, the declaration made upon occasion of requesting market approval would not constitute part of the approval procedure as such and would be directed to competent authorities established under this Regulation.

Amendment

(17) Users should declare at identified points in the chain of activities that they have exercised due diligence. Suitable points for such declarations are the **receipt of research funding, when applying for intellectual property rights at relevant national, regional or international institutions, where** a market approval for a product developed on the basis of genetic resources is requested or at the time of commercialisation where a market approval is not required. Notably, the declaration made upon occasion of requesting market approval would not constitute part of the approval procedure as such and would be directed to competent authorities established under this Regulation.

Or. en

Amendment 97
Pavel Poc

Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) Collecting of genetic resources in the wild is **mostly** undertaken **for non-commercial purposes by university-based** researchers or **collectors**. In the vast majority of cases and in almost all sectors, access to newly collected genetic resources is gained through intermediaries, collections, or agents that acquire genetic resources in third countries.

Amendment

(18) Collecting of genetic resources in the wild is undertaken **by private collectors and companies, often serving commercial purposes, and by academic** researchers or **scientific institutions serving non-commercial purposes**. In the vast majority of cases and in almost all sectors, access to newly collected genetic resources is gained through intermediaries, collections, or agents that acquire genetic resources in third countries.

Justification

It is necessary to clearly differentiate between the public and the private/commercial collectors; the latter are ignored in the original wording, although they are the ones with significant involvement in commercial utilization of genetic resources.

Amendment 98
Gerben-Jan Gerbrandy

Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) Collecting of genetic resources in the wild is **mostly** undertaken for non-commercial purposes by university-based researchers or collectors. In the vast majority of cases and in almost all sectors, access to newly collected genetic resources is gained through intermediaries, collections, or agents that acquire genetic resources in third countries.

Amendment

(18) Collecting of genetic resources in the wild is undertaken **both for commercial purposes and with commercial intent by companies with specific expertise in the field of exploration, harvest and extraction, as well as** for non-commercial purposes by university-based researchers or collectors. In the vast majority of cases and in almost all sectors, access to newly collected genetic resources is gained through intermediaries, collections, or agents that acquire genetic resources in third countries, **both commercially and non-commercially**.

Justification

There are numerous examples, according to TRAFFIC, that (European) companies involved in R&D, including the food, fragrances and pharmaceutical sectors, directly or through intermediaries working in provider countries which provide commercial purposes for the collection of genetic resources from the wild.

Amendment 99
Kriton Arsenis

Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) Collecting of genetic resources in the wild is mostly undertaken for non-commercial purposes by university-based researchers or collectors. In the vast majority of cases and in almost all sectors, access to newly collected genetic resources is gained through intermediaries, collections, or agents that acquire genetic resources in third countries.

Amendment

(18) Collecting of genetic resources in the wild is mostly undertaken for non-commercial purposes by university-based researchers or collectors. In the vast majority of cases and in almost all sectors, access to newly collected genetic resources is gained through intermediaries, collections, or agents that acquire genetic resources in third countries. ***This Regulation should ensure that the provisions of mutually agreed terms for the initial access relevant for third party transfer are followed by all parties involved. To this effect, subsequent utilisation or commercialisation also require prior informed consent and mutually agreed terms.***

Or. en

Amendment 100
Pavel Poc

Proposal for a regulation
Recital 19

Text proposed by the Commission

(19) Collections are major suppliers of genetic resources and traditional knowledge associated with genetic resources used in the Union. A system of Union ***trusted*** collections should be set in place. It would ensure that collections included in the register of Union ***trusted*** collections effectively apply measures to only supply samples of genetic resources to third persons with documentation providing evidence of legal acquisition and the establishment of mutually agreed terms, where required. A system of Union

Amendment

(19) Collections are major suppliers of genetic resources and traditional knowledge associated with genetic resources used in the Union. A system of Union ***registered*** collections should be set in place. It would ensure that collections included in the register of Union ***registered*** collections effectively apply measures to only supply samples of genetic resources to third persons with documentation providing evidence of legal acquisition and the establishment of mutually agreed terms, where required. A system of Union

trusted collections should substantially lower the risk that illegally acquired genetic resources are used in the Union. Competent authorities of Member States would verify if a collection meets the requirements for recognition as Union **trusted** collection. Users that acquire a genetic resource from a collection listed in the Union register should be considered to have exercised due diligence as regards the seeking of all necessary information. This should prove particularly beneficial for academic researchers as well as small and medium sized enterprises.

registered collections should substantially lower the risk that illegally acquired genetic resources are used in the Union. Competent authorities of Member States would verify if a collection meets the requirements for recognition as Union **registered** collection. Users that acquire a genetic resource from a collection listed in the Union register should be considered to have exercised due diligence as regards the seeking of all necessary information. This should prove particularly beneficial for academic researchers as well as small and medium sized enterprises.

Or. en

Justification

Since 'Trusted' is a very loaded term a more neutral term such as 'Registered' would be preferable.

Amendment 101

Cristina Gutiérrez-Cortines, Julie Girling

Proposal for a regulation

Recital 20

Text proposed by the Commission

(20) Competent authorities of Member States should check whether users comply with their obligations. In that context, competent authorities should accept internationally recognised certificates of compliance as evidence that the genetic resources covered were legally acquired and that mutually agreed terms were established. Competent authorities should also keep records of the checks made and relevant information should be made available in accordance with Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental

Amendment

(20) Competent authorities of Member States should check whether users comply with their obligations. In that context, competent authorities should accept internationally recognised certificates of compliance as evidence that the genetic resources covered were legally acquired and that mutually agreed terms were established. ***When an international certificate is not available, other legally acceptable forms of compliance should be considered evidence that the genetic resources covered were legally acquired and that mutually agreed terms were established.*** Competent authorities should

information.¹³

also keep records of the checks made and relevant information should be made available in accordance with Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information.¹³

Or. en

Amendment 102
Kriton Arsenis

Proposal for a regulation
Recital 22 a (new)

Text proposed by the Commission

Amendment

(22a) The principle of benefit-sharing as enshrined in Article 10 of the Nagoya Protocol should be implemented by the Union pending the establishment of a global multilateral mechanism as envisaged in the Protocol. Until global multilateral benefit – sharing mechanism is in place, a Union benefit-sharing fund should be established to collect benefit-sharing contributions and channel them to the conservation of biological diversity globally. To that end, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of detailed criteria and rules for benefit-sharing in situations where genetic resources originate from areas beyond the jurisdiction of the Member States, or the country of origin of such resources cannot be established, or it is not possible to grant or obtain prior informed consent. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and

drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

Or. en

Amendment 103
Anna Rosbach

Proposal for a regulation
Recital 28

Text proposed by the Commission

(28) The objectives of this Regulation are to minimise the risk that illegally genetic resources *or traditional knowledge associated with genetic resources* are used in the Union, and to support the fair and equitable sharing of benefits resulting from the use of *genetic resources or traditional knowledge associated with* genetic resources upon mutually agreed terms. These cannot be achieved by the Member States individually, and can therefore, by reasons of their scale and to ensure functioning of the internal market, be better achieved at Union level. The Union may therefore adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve its objectives.

Amendment

(28) The objectives of this Regulation are to minimise the risk that illegally genetic resources are used in the Union, and to support the fair and equitable sharing of benefits resulting from the use of genetic resources upon mutually agreed terms. These cannot be achieved by the Member States individually, and can therefore, by reasons of their scale and to ensure functioning of the internal market, be better achieved at Union level. The Union may therefore adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve its objectives.

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 104
Anna Rosbach

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission

This Regulation establishes rules governing access and benefit-sharing for **genetic resources and traditional knowledge associated with** genetic resources, in accordance with the provisions of the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation to the Convention on Biological Diversity (the Nagoya Protocol).

Amendment

This Regulation establishes rules governing **compliance with** access and benefit-sharing for genetic resources, in accordance with the provisions of the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation to the Convention on Biological Diversity (the Nagoya Protocol).

Or. en

Justification

The Nagoya Protocol has two pillars: the access pillar and the user-compliance pillar. The scope of this Regulation, however, is not access and benefit-sharing as such but rather how users will comply with the relevant provisions laid down in the Nagoya Protocol.

Amendment 105
Maria do Céu Patrão Neves

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission

This Regulation establishes rules governing access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources, in accordance with the provisions of the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation to the Convention on

Amendment

This Regulation establishes rules governing **compliance with** access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources, in accordance with the provisions of the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation to the Convention on

Biological Diversity (the Nagoya Protocol).

Biological Diversity (the Nagoya Protocol).

Or. en

Amendment 106

Pavel Poc, Cristina Gutiérrez-Cortines

Proposal for a regulation

Article 1 – paragraph 1

Text proposed by the Commission

This Regulation establishes rules governing access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources, in accordance with the provisions of the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation to the Convention on Biological Diversity (the Nagoya Protocol).

Amendment

This Regulation establishes rules governing **compliance with** access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources, in accordance with the provisions of the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation to the Convention on Biological Diversity (the Nagoya Protocol).

Or. en

Justification

The Nagoya Protocol has two pillars: the access pillar and the user-compliance pillar, as also set out in the explanatory memorandum to the Commission's proposal. The scope of this Regulation, however, is not access and benefit-sharing as such but rather how users will comply with the relevant provisions laid down in the Nagoya Protocol.

Amendment 107

Christa Klaß, Herbert Dorfmann, Elisabeth Jeggle, Elisabeth Köstinger

Proposal for a regulation

Article 1 – paragraph 1

Text proposed by the Commission

This Regulation establishes rules

Amendment

This Regulation establishes rules

governing access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources, in accordance with the provisions of the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation to the Convention on Biological Diversity (the Nagoya Protocol).

governing *proper* access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources, in accordance with the provisions of the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation to the Convention on Biological Diversity (the Nagoya Protocol).

Or. de

Amendment 108
Anna Rosbach

Proposal for a regulation
Article 2 – paragraph 1

Text proposed by the Commission

This Regulation applies to genetic resources over which states exercise sovereign rights *and to traditional knowledge associated with genetic resources* that are accessed after the entry into force of the Nagoya Protocol for the Union. It also applies to the benefits arising from the use of such *genetic resources and to traditional knowledge associated with* genetic resources.

Amendment

This Regulation applies to genetic resources over which states exercise sovereign rights that are accessed after the entry into force of the Nagoya Protocol for the Union. It also applies to the benefits arising from the use of such genetic resources.

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 109
Kriton Arsenis

Proposal for a regulation
Article 2 – paragraph 1

Text proposed by the Commission

This Regulation applies to genetic resources ***over which states exercise sovereign rights*** and to traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol for the Union. It also applies to the benefits arising from the ***use*** of such genetic resources and to traditional knowledge associated with genetic resources.

Amendment

This Regulation applies to genetic resources and to traditional knowledge associated with genetic resources that are accessed ***or utilised inside or outside of the jurisdiction of the countries of origin*** after the entry into force of the Nagoya Protocol for the Union. It also applies to the benefits arising from the ***utilisation*** of such genetic resources and to traditional knowledge associated with genetic resources, ***as well as subsequent applications and commercialisation.***

Or. en

Justification

It is a fact that vast quantities of genetic resources are available outside the jurisdiction of their countries of origin in the form of commodities that are freely traded. However, the intended purpose of export of these genetic resources is commodity trade rather than their utilization as genetic resources. Therefore it is essential to ensure that the utilization and benefit-sharing of genetic resources accessed outside the jurisdiction of their country of origin fall under the scope of this regulation.

Amendment 110
Thomas Ulmer, Elisabeth Jeggle

Proposal for a regulation
Article 2 – paragraph 2

Text proposed by the Commission

This Regulation does not apply to genetic resources for which access and benefit-sharing is governed by ***a*** specialised international instrument to which the Union is a Party.

Amendment

This Regulation does not apply to genetic resources for which access and benefit-sharing is governed by specialised international ***instruments*** to which the Union is a Party.

Or. de

Amendment 111
Gaston Franco

Proposal for a regulation
Article 2 – paragraph 2

Text proposed by the Commission

This Regulation does not apply to genetic resources for which access and benefit-sharing is governed by a specialised international instrument to which the Union is a Party.

Amendment

This Regulation does not apply to genetic resources ***from countries which are not signatories of the Nagoya Protocol and which have no access law in conformity with the requirements of the Nagoya Protocol in place. This Regulation does also not apply to genetic resources which are available as commodities, or*** for which access and benefit-sharing is governed by a specialised international instrument to which the Union is a Party. ***Due regard should be paid to useful and relevant ongoing work or practices under other international organisations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.***

Or. en

Justification

The scope of the Regulation should be clarified, especially with regards to the status of commodities: commodities which are available in the normal channels of trade without any restrictions should continue to be available without restrictions and therefore explicitly excluded from the draft Regulation. In addition, the second paragraph of Article 2 of the draft Regulation should be extended so that it also covers any on-going work or practices as described under Article 4.3 of the Nagoya Protocol.

Amendment 112
Thomas Ulmer, Elisabeth Jeggle

Proposal for a regulation
Article 2 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

Given the specific nature of biodiversity in the agricultural sphere, its characteristics and its problems, which call for specific solutions, this Regulation shall not apply to genetic resources for food and agriculture in so far as these fall within the scope of existing or future specialised instruments under Articles 4, 8c, 19 and 20 of the Nagoya Protocol.

Or. de

Amendment 113

Cristina Gutiérrez-Cortines, Santiago Fisas Ayxela

Proposal for a regulation

Article 3 – paragraph 1 –point 1 a (new)

Text proposed by the Commission

Amendment

(1a) Definition of catalogue: genetic catalogues are made of individuals belonging to certain species. The next items of importance are local populations (landraces, ecotypes, endemism's, varieties, or even subspecies). Genetic catalogues require as for traceability an unbiased method of bar-coding that should be based on DNA sequencing technologies.

Or. en

Amendment 114

Pavel Poc, Cristina Gutiérrez-Cortines

Proposal for a regulation

Article 3 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

(1a) "commercialisation" means the first making available of a product on the Community market.

Or. en

Justification

Legal clarity is needed regarding the term 'commercialisation'; the proposed definition is in line with the definition of 'placing on the market' in various pieces of EU legislation, such as the Cosmetic Products Regulation (EC) N° 1223/2009 and the proposals for Consumer Product Safety and Market Surveillance of Products Regulations, respectively.

Amendment 115

Cristina Gutiérrez-Cortines, Santiago Fisas Ayxela

Proposal for a regulation

Article 3 – paragraph 1 – point 1 b (new)

Text proposed by the Commission

Amendment

(1b) Concept of traceability: genetic items have to be defined at the molecular level with enough resolution to allow the unequivocal identification of its origin and destiny. Although a protocol of traceability requires a proper pipe of events or usage for any item, the traceability of any genetic entity requires its fingerprinting at the DNA level.

Or. en

Amendment 116

Anna Rosbach

Proposal for a regulation

Article 3 – paragraph 1 – point 4

Text proposed by the Commission

Amendment

(4) "access" means the acquisition of genetic resources *or of traditional knowledge associated with genetic resources* in a Party to the Nagoya Protocol in accordance with the applicable domestic access and benefit-sharing legislation or regulatory requirements of that Party.

(4) "access" means the acquisition of genetic resources in a Party to the Nagoya Protocol in accordance with the applicable domestic access and benefit-sharing legislation or regulatory requirements of that Party.

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 117
Anna Rosbach

Proposal for a regulation
Article 3 – paragraph 1 – point 5

Text proposed by the Commission

Amendment

(5) "user" means a natural or legal person using genetic resources *or traditional knowledge associated with genetic resources*;

(5) "user" means a natural or legal person using genetic resources;

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 118
Anna Rosbach

Proposal for a regulation
Article 3 – paragraph 1 – point 7

Text proposed by the Commission

(7) "mutually agreed terms" means the contractual arrangement concluded between a provider of genetic resources ***or of traditional knowledge associated with genetic resources*** and a user of such resources or knowledge, that sets out specific conditions for the fair and equitable sharing of benefits arising from such use, and that may also include further conditions and terms for the use of such resources or knowledge;

Amendment

(7) "mutually agreed terms" means the contractual arrangement concluded between a provider of genetic resources and a user of such resources or knowledge, that sets out specific conditions for the fair and equitable sharing of benefits arising from such use, and that may also include further conditions and terms for the use of such resources or knowledge;

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation

Amendment 119
Anna Rosbach

Proposal for a regulation
Article 3 – paragraph 1 – point 8

Text proposed by the Commission

(8) "traditional knowledge associated with genetic resources" means traditional knowledge held by an indigenous or local community that is relevant for the use of genetic resources and that is as such described in the mutually agreed terms applying to the use of genetic resources;

Amendment

deleted

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the

Regulation.

Amendment 120
Kriton Arsenis

Proposal for a regulation
Article 3 – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

(8a) "illegally acquired genetic resources" means genetic resources and traditional knowledge associated with genetic resources acquired in contravention of the applicable international and national legislation or regulatory requirements on access and benefit-sharing in the country of origin, or the applicable customary laws, protocols and procedures of indigenous and local communities.

Or. en

Justification

The wording is in line with Article 12 of the Nagoya Protocol. Valid prior informed consent for access to traditional knowledge cannot be obtained in contravention of the applicable customary laws, protocols and procedures of indigenous peoples and local communities which must be taken into consideration by national authorities in the implementation of the Protocol.

Amendment 121
Kriton Arsenis

Proposal for a regulation
Article 3 – paragraph 1 – point 8 b (new)

Text proposed by the Commission

Amendment

(8b) "biopiracy" means utilisation, or subsequent commercialisation, of illegally acquired genetic resources or products derived from such resources or traditional

knowledge associated with genetic resources.

Or. en

Amendment 122

Gaston Franco

Proposal for a regulation

Article 3 – paragraph 1 – point 12 a (new)

Text proposed by the Commission

Amendment

(12a) "commodity" means, for the purposes of this Regulation, a genetic resource freely traded as a product of commerce.

Or. en

Justification

In order to complete Amendment 1 (Article 2), which clarifies that commodities which are available in the normal channels of trade without any restrictions should continue to be available without restrictions and therefore explicitly excluded from the draft Regulation, we propose to add a definition of "commodities".

Amendment 123

Gaston Franco

Proposal for a regulation

Article 3 – paragraph 1 – point 12 b (new)

Text proposed by the Commission

Amendment

(12b) "research and development" means the investigation and study of the genetic or biochemical composition of genetic resources in order to establish facts and reach conclusions, including the creation of innovations and practical applications. This does not cover any scientific work carried out for compliance with health

and safety regulatory requirements.

Or. en

Justification

The definition of “research and development” should be used in the context of the Nagoya Protocol. However, an additional sentence is necessary in order to avoid any potential misinterpretation of the definition or confusion with tests or studies carried out to meet regulatory requirements related to health and safety.

Amendment 124
Anna Rosbach

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission

1. Users shall exercise due diligence to ascertain that genetic resources ***and traditional knowledge associated with genetic resources*** used were accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements and that, where relevant, benefits are fairly and equitably shared upon mutually agreed terms. Users shall seek, keep, and transfer to subsequent users information relevant for access and benefit-sharing.

Amendment

1. Users shall exercise due diligence to ascertain that genetic resources used were accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements and that, where relevant, benefits are fairly and equitably shared upon mutually agreed terms. Users shall seek, keep, and transfer to subsequent users information relevant for access and benefit-sharing.

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 125
Gerben-Jan Gerbrandy

Proposal for a regulation
Article 4 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. Illegally acquired genetic resources shall be prohibited in the Union.

Or. en

Justification

The due diligence system the Commission puts in place needs to be accompanied by a general prohibition on the illegal use of genetic resources. This reverses the burden of proof, as is already the case for illegal timber (Regulation (EU) No. 95/2010) and IUU fishing, facilitating the judicial process and enforcement by the respective competent national authorities.

Amendment 126
Thomas Ulmer, Elisabeth Jeggle

Proposal for a regulation
Article 4 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The due diligence referred to in paragraph 1 shall not apply to subsequent uses of the product developed from the original resource (e.g. a plant variety) if the product is not a usable genetic resource.

Or. de

Amendment 127
Kriton Arsenis

Proposal for a regulation
Article 4 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. In the case of genetic resources originating from areas beyond national jurisdictions, or where the country of origin cannot be established, or where it is not possible to grant or obtain prior informed consent, new users shall provide benefit-sharing to a Union benefit-sharing fund dedicated to the conservation of biological diversity globally, until a global multilateral benefit-sharing mechanism is established pursuant to Article 10 of the Nagoya Protocol.

Or. en

Amendment 128

Anna Rosbach

Proposal for a regulation

Article 4 – paragraph 2 – point a – point 1

Text proposed by the Commission

Amendment

(1) the date and place of access of genetic resources ***and traditional knowledge associated with such resources;***

(1) the date and place of access of genetic resources;

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation

Amendment 129

Cristina Gutiérrez-Cortines, Santiago Fisas Ayxela

Proposal for a regulation

Article 4 – paragraph 2 – point a – point 1 a (new)

Text proposed by the Commission

Amendment

(1a) The internationally recognised certificate of compliance, in the case of genetic resources acquired from Parties to the Nagoya Protocol that have regulated access to their genetic resources in compliance with Article 6 of the Nagoya Protocol, or,

Or. en

Amendment 130

Anna Rosbach

Proposal for a regulation

Article 4 – paragraph 2 – point a – point 2

Text proposed by the Commission

Amendment

(2) the description of genetic resources ***or traditional knowledge associated with such resources*** used, including available unique identifiers;

(2) the description of genetic resources used, including available unique identifiers;

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 131

Christa Klaß, Herbert Dorfmann, Elisabeth Jeggle, Elisabeth Köstinger, Esther de Lange

Proposal for a regulation

Article 4 – paragraph 2 – point a – point 3

Text proposed by the Commission

Amendment

(3) the source from which the resources or the knowledge were directly obtained ***as***

(3) the source from which the resources or

well as subsequent users of genetic resources or traditional knowledge associated with such resources;

the knowledge were directly obtained;

Or. de

Amendment 132

Christa Klaß, Herbert Dorfmann, Elisabeth Jeggle, Elisabeth Köstinger

Proposal for a regulation

Article 4 – paragraph 2 – point a – point 5

Text proposed by the Commission

Amendment

(5) access *decisions* and mutually agreed terms, where applicable;

(5) access *permits* and mutually agreed terms, where applicable;

Or. de

Amendment 133

Maria do Céu Patrão Neves

Proposal for a regulation

Article 4 – paragraph 2 – point a – point 5

Text proposed by the Commission

Amendment

(5) access *decisions* and mutually agreed terms, where applicable;

(5) access *permits* and mutually agreed terms, where applicable;

Or. en

Amendment 134

Pavel Poc

Proposal for a regulation

Article 4 – paragraph 2 – point a – point 5

Text proposed by the Commission

Amendment

(5) access *decisions* and mutually agreed terms, where applicable;

(5) access *permits* and mutually agreed terms, where applicable;

Justification

The term “permit” is the terminology used in the Nagoya protocol as well as throughout the regulation itself. Therefore it is opportune to harmonize the terminology in order to avoid confusion.

Amendment 135

Cristina Gutiérrez-Cortines, Julie Girling

Proposal for a regulation

Article 4 – paragraph 2 – point a – point 5

Text proposed by the Commission

(5) access **decisions** and mutually agreed terms, where applicable;

Amendment

(5) access **permits** and mutually agreed terms, where applicable;

Or. en

Amendment 136

Christa Klaß, Herbert Dorfmann, Elisabeth Jeggle, Elisabeth Köstinger

Proposal for a regulation

Article 4 – paragraph 2 – point c

Text proposed by the Commission

(c) obtain a proper access permit, establish mutually agreed terms, **or discontinue the use** where it appears that access was not in accordance with applicable access and benefit-sharing legislation or regulatory requirements.

Amendment

(c) obtain a proper access permit **and** establish mutually agreed terms where it appears that access was not in accordance with applicable access and benefit-sharing legislation or regulatory requirements.

Or. de

Amendment 137

Anna Rosbach

Proposal for a regulation
Article 4 – paragraph 4

Text proposed by the Commission

4. Users acquiring a genetic resource from a collection listed in the Union register of trusted collections referred to in Article 5(1) shall be considered to have exercised due diligence as regards the seeking of information relevant to access and benefit-sharing for genetic resources **and traditional knowledge associated with genetic resources.**

Amendment

4. Users acquiring a genetic resource from a collection listed in the Union register of trusted collections referred to in Article 5(1) shall be considered to have exercised due diligence as regards the seeking of information relevant to access and benefit-sharing for genetic resources.

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 138
Pavel Poc

Proposal for a regulation
Article 4 – paragraph 4

Text proposed by the Commission

4. Users acquiring a genetic resource from a collection listed in the Union register of **trusted** collections referred to in Article 5(1) shall be considered to have exercised due diligence as regards the seeking of information relevant to access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources.

Amendment

4. Users acquiring a genetic resource from a collection listed in the Union register of collections referred to in Article 5(1) shall be considered to have exercised due diligence as regards the seeking of information relevant to access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources.

Or. en

Justification

The proposed amendment to the term “Union Registered Collections” follows previous

amendments as proposed in Recital 19.

Amendment 139

Christa Klaß, Elisabeth Jeggle, Elisabeth Köstinger, Herbert Dorfmann, Esther de Lange

Proposal for a regulation

Article 4 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. The obligations referred to in paragraphs 1 to 3 of this Article shall apply to subsequent users only if they access and use genetic resources in the same way as the initial user.

Or. de

Amendment 140

Sophie Auconie

Proposal for a regulation

Article 4 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. Where a genetic resource has been incorporated into a new plant variety that has been placed on the market, the requirements set out in paragraphs 1 to 3 shall not apply to users of that new plant variety. The requirements applicable to the first user incorporating the genetic resource are therefore waived.

Or. fr

Justification

Article 4 does not take into account seed research. When creating new plant varieties, plant breeders utilise genetic resources (including plant varieties already on the market) and are therefore subject to this regulation. However, since checks will already have been run to

ensure that plant breeders have complied with the protocol when a variety is placed on the market, anyone utilising that variety for research purposes should be exempt from such requirements.

Amendment 141
Cristina Gutiérrez-Cortines

Proposal for a regulation
Article 5

Text proposed by the Commission

Amendment

Article 5

deleted

Union trusted collections

1. The Commission shall establish and maintain a Union register of trusted collections. That register shall be internet-based, easily accessible to users, and shall include the collections of genetic resources identified as meeting the criteria of Union trusted collection.

2. Each Member State shall, upon request by a collection under its jurisdiction, consider the inclusion of this collection in the Union register of trusted collections. After verifying that the collection meets the criteria set out in paragraph 3, the Member State shall notify the Commission without delay of that collection's name, contact details, and type. The Commission shall without delay include the information thus received into the Union register of trusted collections.

3. In order for a collection to be included in the Union register of trusted collections, a collection owner shall demonstrate its capacity to:

(a) apply standardised procedures for exchanging samples of genetic resources and related information with other collections, and for supplying samples of genetic resources and related information to third persons for their use;

(b) have samples of genetic resources and related information supplied to third

persons for their use only with documentation providing evidence that the resources and the information were accessed in accordance with applicable legal requirements and, where relevant, mutually agreed terms for the fair and equitable sharing of benefits;

(c) keep records of all samples of genetic resources and related information supplied to third persons for their use;

(d) establish or use unique identifiers for samples of genetic resources supplied to third persons;

(e) use appropriate tracking and monitoring tools for exchanging samples of genetic resources and related information with other collections.

4. Member States shall regularly verify that each collection under their jurisdiction included in the Union register of trusted collections effectively applies the measures set out in paragraph 3.

Member States shall inform the Commission without delay if a collection under their jurisdiction included in the Union register no longer complies with paragraph 3.

5. Where there is evidence that a collection included in the Union register of trusted collections does not apply the measures set out in paragraph 3, the Member State concerned shall without delay identify remedial actions in dialogue with the owner of the collection concerned.

The Commission shall remove a collection from the Union register of trusted collections when, in particular on the basis of information provided pursuant to paragraph 4, it has determined that a collection included in the Union register of trusted collections faces important or persistent difficulties to comply with paragraph 3.

6. The Commission shall be empowered to adopt implementing acts to establish the procedures for implementing paragraphs 1 to 5 of this Article. The implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).

Or. en

Amendment 142
Pavel Poc

Proposal for a regulation
Article 5 – title

Text proposed by the Commission

Amendment

Union **trusted** collections

Union **registered** collections

Or. en

Justification

The proposed amendment to the term “Union Registered Collections” follows previous amendments as proposed in Recital 19.

Amendment 143
Pavel Poc

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission

Amendment

1. The Commission shall establish and maintain a Union register of **trusted** collections. That register shall be internet-based, easily accessible to users, and shall include the collections of genetic resources identified as meeting the criteria of Union **trusted** collection.

1. The Commission shall establish and maintain a Union register of collections. That register shall be internet-based, easily accessible to users, and shall include the collections of genetic resources identified as meeting the criteria of Union **registered** collection.

Justification

The proposed amendment to the term “Union Registered Collections” follows previous amendments as proposed in Recital 19.

Amendment 144**Pavel Poc****Proposal for a regulation****Article 5 – paragraph 2***Text proposed by the Commission*

2. Each Member State shall, upon request by a collection under its jurisdiction, consider the inclusion of this collection in the Union register of **trusted** collections. After verifying that the collection meets the criteria set out in paragraph 3, the Member State shall notify the Commission without delay of that collection's name, contact details, and type. The Commission shall without delay include the information thus received into the Union **register of trusted** collections.

Amendment

2. Each Member State shall, upon request by a collection **holder** under its jurisdiction, consider the inclusion of this collection, **or part of it**, in the Union register of collections. After verifying that the collection meets the criteria set out in paragraph 3, the Member State shall notify the Commission without delay of that collection's name, contact details, and type. The Commission shall without delay include the information thus received into the Union **registered** collections.

Justification

The proposed addition of “or part of it”, reflects the fact that only a very small part of existing public collections could fulfil requirements set out in the Regulation for Union Trusted/Registered Collections. The proposed amendment to the term “Union Registered Collections” follows previous amendments as proposed in Recital 19.

Amendment 145**Pavel Poc****Proposal for a regulation****Article 5 – paragraph 3 – introductory part**

Text proposed by the Commission

Amendment

3. In order for a collection to be included in the Union register of trusted collections, a collection owner shall demonstrate its capacity to:

3. In order for a collection to be included in the Union register of trusted collections, a collection owner shall, ***in regard to specimens accessed according to Article 2 of this Regulation***, demonstrate its capacity to:

Or. en

Justification

By restricting the coverage of Article 5 in this sense, only samples accessed after entry into force of the Nagoya Protocol would fulfil the provisions of Article 4(4).

Amendment 146

Pavel Poc

Proposal for a regulation

Article 5 – paragraph 4 – subparagraph 1

Text proposed by the Commission

Amendment

Member States shall regularly verify that each collection under their jurisdiction included in the Union register of ***trusted*** collections effectively applies the measures set out in paragraph 3.

Member States shall regularly verify that each collection under their jurisdiction included in the Union register of collections effectively applies the measures set out in paragraph 3.

Or. en

Justification

The proposed amendment to the term “Union Registered Collections” follows previous amendments as proposed in Recital 19.

Amendment 147

Pavel Poc

Proposal for a regulation

Article 5 – paragraph 5 – subparagraph 1

Text proposed by the Commission

Where there is evidence that a collection included in the Union register of **trusted** collections does not apply the measures set out in paragraph 3, the Member State concerned shall without delay identify remedial actions in dialogue with the owner of the collection concerned.

Amendment

Where there is evidence that a collection included in the Union register of collections does not apply the measures set out in paragraph 3, the Member State concerned shall without delay identify remedial actions in dialogue with the owner of the collection concerned.

Or. en

Justification

The proposed amendment to the term “Union Registered Collections” follows previous amendments as proposed in Recital 19.

Amendment 148

Pavel Poc

Proposal for a regulation

Article 5 – paragraph 5 – subparagraph 2

Text proposed by the Commission

The Commission shall remove a collection from the Union register of **trusted** collections when, in particular on the basis of information provided pursuant to paragraph 4, it has determined that a collection included in the Union register of **trusted** collections faces important or persistent difficulties to comply with paragraph 3.

Amendment

The Commission shall remove a collection from the Union register of collections when, in particular on the basis of information provided pursuant to paragraph 4, it has determined that a collection included in the Union register of collections faces important or persistent difficulties to comply with paragraph 3.

Or. en

Justification

The proposed amendment to the term “Union Registered Collections” follows previous amendments as proposed in Recital 19.

Amendment 149
Anna Rosbach

Proposal for a regulation
Article 5 – paragraph 6

Text proposed by the Commission

6. The Commission shall **be empowered to** adopt implementing acts to establish the procedures for implementing paragraphs 1 to 5 of this Article. **The** implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).

Amendment

6. The Commission shall adopt implementing acts to establish the procedures for implementing paragraphs 1 to 5 of this Article, **as well as to consider procedures for registering collections located in third countries that fulfil the criteria for Union Trusted Collections so as to support global implementation of the Nagoya Protocol. Those** implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).

Or. en

Justification

The proposal for Trusted Collections should include a mechanism to enable Member States and the Commission to consider possible application of this element to collections outside of the EU. This reflects the partnerships that exist between collections and will support international cooperation.

Amendment 150
Gerben-Jan Gerbrandy

Proposal for a regulation
Article 5 – paragraph 6

Text proposed by the Commission

6. The Commission shall be empowered to adopt implementing acts to establish the procedures for implementing paragraphs 1 to 5 of this Article. The implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).

Amendment

6. The Commission shall be empowered to adopt implementing acts to establish the procedures for implementing paragraphs 1 to 5 of this Article, **and to consider proposing procedures for registering collections located in third countries that fulfil the criteria for Union Trusted**

Collections so as to support global implementation of the Nagoya Protocol.
The implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).

Or. en

Justification

This amendment is self-explanatory, but comes from the Permanent Representation. They had two other amendments as well, but those would have had the effect of excluding the entire agriculture sector. That surely cannot really be the intention – particularly because I cannot be sure of all the consequences that the exclusion of such a large sector would have. They might do better to get the amendments incorporated in the Council proposals: then we can always support them in the trialogue.

Amendment 151

Anna Rosbach

Proposal for a regulation

Article 6 – paragraph 3

Text proposed by the Commission

3. The Commission shall designate a focal point on access and benefit-sharing responsible for providing information to applicants seeking access to genetic resources ***and traditional knowledge associated with such resources*** in the Union and to liaise with the Secretariat of the Convention on Biological Diversity.

Amendment

3. The Commission shall designate a focal point on access and benefit-sharing responsible for providing information to applicants seeking access to genetic resources in the Union and to liaise with the Secretariat of the Convention on Biological Diversity.

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 152

Gerben-Jan Gerbrandy

Proposal for a regulation
Article 6 – paragraph 3 – point 1 (new)

Text proposed by the Commission

Amendment

(1) The focus point designated by the Commission in point 3, shall ensure consultation with the relevant Union bodies established under, and national authorities implementing, Regulation (EC) No.338/97.

Or. en

Justification

Regulation (EC) No. 338/97 "on the protection of species of wild fauna and flora by regulating trade therein", is commonly known as the EU Wildlife Trade Regulation. Setting up a mechanism to ensure effective coordination between national authorities responsible for the implementation of CITES and the Nagoya Protocol is essential to efficiently address both illegal and unsustainable trade.

Amendment 153
Anna Rosbach

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission

Amendment

1. Member States and the Commission shall request all recipients of public research funding involving uses of genetic resources **and traditional knowledge associated with genetic resources** to declare that they will exercise due diligence in accordance with Article 4.

1. Member States and the Commission shall request all recipients of public research funding involving uses of genetic resources to declare that they will exercise due diligence in accordance with Article 4.

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 154
Cristina Gutiérrez-Cortines

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission

1. **Member States and the Commission shall request** all recipients of public research funding involving **uses** of genetic resources and traditional knowledge associated with genetic resources to declare that they will **exercise due diligence in accordance with** Article 4.

Amendment

1. All recipients of public research funding involving **the utilization** of genetic resources and **or of** traditional knowledge associated with genetic resources **shall, upon approval of such funding, declare to the funding authority** that they will **fulfil or have fulfilled their obligations under** Article 4.

Or. en

Amendment 155
Cristina Gutiérrez-Cortines

Proposal for a regulation
Article 7 – paragraph 2

Text proposed by the Commission

2. **Users shall declare to the competent authorities established under Article 6(1) that they exercised due diligence in accordance with Article 4 on the occasion of requesting market approval for a product developed on the basis of genetic resources or traditional knowledge associated with such resources, or at the time of commercialisation** where a market approval is not required.

Amendment

2. **Member States and the Commission shall request users seeking market approval for a product developed via the use of genetic resources or traditional knowledge associated with genetic resources to declare and provide evidence that they have fulfilled the obligations under Article 4. They shall equally request such information before the product is placed on the market** where a market approval is not required.

Or. en

Amendment 156
Thomas Ulmer, Elisabeth Jeggle

Proposal for a regulation
Article 7 – paragraph 2

Text proposed by the Commission

2. Users shall declare to the competent authorities established under Article 6(1) that they exercised due diligence in accordance with Article 4 on the occasion of requesting market approval for a product developed on the basis of genetic resources or traditional knowledge associated with such resources, or at the time of commercialisation where a market approval is not required.

Amendment

2. Users shall declare to the competent authorities established under Article 6(1) that they exercised due diligence in accordance with Article 4 on the occasion of requesting market approval for a product developed on the basis of genetic resources or traditional knowledge associated with such resources, or at the time of commercialisation where a market approval is not required. ***This declaration shall not be required if the country of origin of the genetic resource used does not insist on Prior Informed Consent and Mutually Agreed Terms in accordance with Article 6 of the Nagoya Protocol.***

Or. de

Amendment 157
Anna Rosbach

Proposal for a regulation
Article 7 – paragraph 2

Text proposed by the Commission

2. Users shall declare to the competent authorities established under Article 6(1) that they exercised due diligence in accordance with Article 4 on the occasion of requesting market approval for a product developed on the basis of genetic resources ***or traditional knowledge associated with such resources***, or at the time of commercialisation where a market approval is not required.

Amendment

2. Users shall declare to the competent authorities established under Article 6(1) that they exercised due diligence in accordance with Article 4 on the occasion of requesting market approval for a product developed on the basis of genetic resources, or at the time of commercialisation where a market approval is not required.

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 158 **Cristina Gutiérrez-Cortines**

Proposal for a regulation **Article 7 – paragraph 3**

Text proposed by the Commission

3. Competent authorities shall transmit to the *Commission every two years the information received on the basis of paragraphs 1 and 2. The Commission shall summarise* the information received *and make it available to the Access and Benefit-sharing Clearing House.*

Amendment

3. Competent authorities shall transmit to the *Access and Benefit Sharing Clearing House Mechanism, to the Commission and/or the competent authorities of the State concerned* the information received *on the basis of paragraph 1 and 2.*

Or. en

Amendment 159 **Cristina Gutiérrez-Cortines, Pavel Poc**

Proposal for a regulation **Article 8**

Text proposed by the Commission

Article 8 *Best practices*

1. Any association of users may submit an application to the Commission for recognising as best practice a combination of procedures, tools or mechanisms developed and overseen by it. The application shall be supported by evidence and information.

2. Where, on the basis of information and evidence supplied to it by an association of users , the Commission determines that

Amendment

deleted

the specific combination of procedures, tools or mechanisms, when effectively implemented by a user, enables the user to comply with its obligations set out in Articles 4 and 7, it shall grant recognition as best practice.

3. An association of users shall inform the Commission of any changes or updates made to a recognised best practice for which it was granted recognition in accordance with paragraph 2.

4. If evidence from competent authorities of the Member States or other sources indicates repeated cases where users implementing a best practice fail to comply with their obligations under this Regulation, the Commission shall examine in dialogue with the relevant association of users whether the repeated cases of non-compliance indicate possible deficiencies in the best practice.

5. The Commission shall withdraw the recognition of a best practice, when it has determined that changes to the best practice compromise a user's ability to meet the conditions set out in Articles 4 and 7, or when repeated cases of non-compliance by users relate to deficiencies in the practice.

6. The Commission shall establish and keep up to date an internet-based register of recognised best practices. That register shall list in one section best practices recognised by the Commission in accordance with paragraph 2 of this Article and display in another section best practices adopted on the basis of Article 20(2) Nagoya Protocol.

7. The Commission shall be empowered to adopt implementing acts to establish the procedures for implementing paragraphs 1 to 5 of this Article. The implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).

Amendment 160
Cristina Gutiérrez-Cortines, Santiago Fisas Ayxela

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission

Amendment

2. The checks referred to in paragraph 1 of this Article shall be conducted in accordance with a periodically reviewed plan following a risk-based approach. When developing this risk-based approach, Member States shall consider that the implementation by a user of a best practice recognised under Article 8(2) of this Regulation or under Article 20(2) of the Nagoya Protocol reduces that user's risk of non-compliance. **deleted**

Amendment 161
Christa Klauf, Herbert Dorfmann, Elisabeth Jeggle, Elisabeth Köstinger

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission

Amendment

2. The checks referred to in paragraph 1 of this Article shall be conducted in accordance with a periodically reviewed plan following a risk-based approach. **When developing this risk-based approach, Member States shall consider that the implementation by a user of a best practice recognised under Article 8(2) of this Regulation or under Article 20(2) of the Nagoya Protocol reduces that user's risk of non-compliance.**

2. The checks referred to in paragraph 1 of this Article shall be conducted in accordance with a periodically reviewed plan following a risk-based approach **the key principles of which shall be laid down by the Commission in accordance with the procedure set out in Article 15(2). This approach shall take into account the fact that the implementation by a user of a best practice recognised under Article 8(2) of this Regulation or under Article 20(2) of the Nagoya Protocol reduces that user's**

risk of non-compliance.

Or. de

Amendment 162

Maria do Céu Patrão Neves

Proposal for a regulation

Article 9 – paragraph 2

Text proposed by the Commission

2. The checks referred to in paragraph 1 of this Article shall be conducted in accordance with a periodically reviewed plan following a risk-based approach. When developing this risk-based approach, **Member States** shall **consider** that the implementation by a user of a best practice recognised under Article 8(2) of this Regulation or under Article 20(2) of the Nagoya Protocol reduces that user's risk of non-compliance.

Amendment

2. The checks referred to in paragraph 1 of this Article shall be conducted in accordance with a periodically reviewed plan following a risk-based approach. When developing this risk-based approach, **the key principles shall be laid down by the Commission in accordance with the procedure referred to in Article 15(2). Such an approach shall take into account** that the implementation by a user of a best practice recognised under Article 8(2) of this Regulation or under Article 20(2) of the Nagoya Protocol reduces that user's risk of non-compliance.

Or. en

Amendment 163

Pavel Poc

Proposal for a regulation

Article 9 – paragraph 2

Text proposed by the Commission

2. The checks referred to in paragraph 1 of this Article shall be conducted in accordance with a periodically reviewed plan following a risk-based approach. **When developing this risk-based approach, Member States shall consider** that the implementation by a user of a best

Amendment

2. The checks referred to in paragraph 1 of this Article shall be conducted in accordance with a periodically reviewed plan following a risk-based approach **of which the key principles shall be laid down by the Commission in accordance with the procedure referred to in Article**

practice recognised under Article 8(2) of this Regulation or under Article 20(2) of the Nagoya Protocol reduces that user's risk of non-compliance.

15(2). Such an approach shall **take into account** that the implementation by a user of a best practice recognised under Article 8(2) of this Regulation or under Article 20(2) of the Nagoya Protocol reduces that user's risk of non-compliance.

Or. en

Justification

In order to avoid distortions on the market within the EU, the risk-based approach, or at least the principles thereof, should be developed in a centralised manner by the Commission.

Amendment 164

Cristina Gutiérrez-Cortines, Santiago Fisas Ayxela, Julie Girling

Proposal for a regulation Article 9 – paragraph 3

Text proposed by the Commission

3. Checks **may** be conducted when a competent authority is in possession of relevant information, including on the basis of substantiated concerns provided by third parties, concerning non-compliance of a user with this Regulation.

Amendment

3. Checks **shall** be conducted when a competent authority is in possession of relevant information, including on the basis of substantiated concerns provided by third parties, concerning **a user's** non-compliance of a user with this Regulation.

Or. en

Amendment 165

Christa Klaß, Herbert Dorfmann, Elisabeth Jeggle, Elisabeth Köstinger

Proposal for a regulation Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The checks referred to in paragraph 1 shall include **at least**:

Amendment

4. The checks referred to in paragraph 1 shall include:

Or. de

Amendment 166

Maria do Céu Patrão Neves

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The checks referred to in paragraph 1 shall include *at least*:

Amendment

4. The checks referred to in paragraph 1 shall include:

Or. en

Amendment 167

Christa Klaß, Elisabeth Jeggle, Elisabeth Köstinger, Herbert Dorfmann

Proposal for a regulation

Article 9 – paragraph 4 – point c

Text proposed by the Commission

(c) on the spot checks, *including field audits*;

Amendment

(c) on the spot checks;

Or. de

Amendment 168

Cristina Gutiérrez-Cortines, Julie Girling

Proposal for a regulation

Article 9 – paragraph 5

Text proposed by the Commission

5. Competent authorities shall accept an internationally recognised certificate of compliance as evidence that the genetic resource it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or

Amendment

5. Competent authorities shall accept an internationally recognised certificate of compliance as evidence that the genetic resource it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or

regulatory requirements of the Party to the Nagoya Protocol providing the prior informed consent.

regulatory requirements of the Party to the Nagoya Protocol providing the prior informed consent. ***In the event that an internationally recognised certificate is not available, other legally acceptable forms of compliance should be considered enough evidence that the genetic resources covered were legally obtained and that mutually agreed terms were established.***

Or. en

Amendment 169
Julie Girling

Proposal for a regulation
Article 9 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. The Implementing Rules will define procedural safeguards with respect to the procedures under Articles 7 and 9 to 11.

Or. en

Justification

In accordance with the legal principle of due process and the Nagoya Protocol, it is essential that procedural safeguards and processes, such as the right to be heard or to appeal any decisions made under Articles 7 and 9 to 11, to protect the rights of those who are being regulated are put in place in the Regulation, especially since non-compliance will be sanctioned by effective and dissuasive penalties.

Amendment 170
Cristina Gutiérrez-Cortines, Julie Girling

Proposal for a regulation
Article 9 – paragraph 6

Text proposed by the Commission

Amendment

6. Users shall offer all assistance necessary to facilitate the performance of the checks referred to in paragraph 1, ***notably as regards access to premises and the presentation of documentation or records.***

6. Users shall offer all assistance necessary to facilitate the performance of the checks referred to in paragraph 1.

Or. en

Amendment 171
Anna Rosbach

Proposal for a regulation
Article 9 – paragraph 7 – subparagraph 2

Text proposed by the Commission

Amendment

Additionally, depending on the nature of the shortcomings detected, Member States may take immediate interim measures, including inter alia seizure of illegally acquired genetic resources and suspension of specific use activities.

Additionally, depending on the nature of the shortcomings detected, Member States may take immediate interim measures, including inter alia seizure of illegally acquired genetic resources and suspension of specific use activities. ***These interim measures must be effective, proportionate and dissuasive.***

Or. en

Justification

As stipulated in Article 11(2), it should be clarified that the principle of effective, proportionate and dissuasive sanctions must also apply to interim measures.

Amendment 172
Pavel Poc

Proposal for a regulation
Article 9 – paragraph 7 – subparagraph 2

Text proposed by the Commission

Amendment

Additionally, depending on the nature of

Additionally, depending on the nature of

the shortcomings detected, Member States may take immediate interim measures, including inter alia seizure of illegally acquired genetic resources and suspension of specific use activities.

the shortcomings detected, Member States may take immediate interim measures, including inter alia seizure of illegally acquired genetic resources and suspension of specific use activities. ***Such interim measures must be effective, proportionate and dissuasive.***

Or. en

Justification

As also specified in Article 11(2) of the Commission's proposal, it has to be clarified that the principle of effective, proportionate and dissuasive sanctions should also apply to interim measures.

Amendment 173

Cristina Gutiérrez-Cortines, Julie Girling

Proposal for a regulation

Article 9 – paragraph 7 – subparagraph 2

Text proposed by the Commission

Additionally, depending on the nature of the shortcomings detected, Member States may take immediate interim measures, including inter alia seizure of illegally acquired genetic resources and suspension of specific use activities.

Amendment

Depending on the nature of the shortcomings detected, Member States may take immediate ***appropriate*** interim measures, including inter alia seizure of illegally acquired genetic resources and suspension of specific use activities.

Or. en

Amendment 174

Cristina Gutiérrez-Cortines

Proposal for a regulation

Article 11 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. Member States shall allow the parties to make allegations or to appeal the

decisions taken under Articles 7 and 9 in cases of alleged infringements.

Or. en

Amendment 175

Christa Klaß, Herbert Dorfmann, Elisabeth Jeggle, Elisabeth Köstinger

Proposal for a regulation

Article 12 – paragraph 2

Text proposed by the Commission

2. The competent authorities shall exchange information on serious shortcomings detected through checks referred to in **Article 9(1)** and on the types of penalties imposed in accordance with Article 11 with the competent authorities of other Member States and with the Commission.

Amendment

2. The competent authorities shall exchange information ***on the organisation of their checking system for monitoring user compliance with this Regulation***, on serious shortcomings detected through checks referred to in ***Articles 9(4) and 10(1)*** and on the types of penalties imposed in accordance with Article 11 with the competent authorities of other Member States and with the Commission.

Or. de

Amendment 176

Maria do Céu Patrão Neves

Proposal for a regulation

Article 12 – paragraph 2

Text proposed by the Commission

2. The competent authorities shall exchange information on serious shortcomings detected through checks referred to in Article 9(1) and on the types of penalties imposed in accordance with Article 11 with the competent authorities of other Member States and with the Commission.

Amendment

2. The competent authorities shall exchange information on ***the organization of their checking system for monitoring user compliance with this Regulation and on*** serious shortcomings detected through checks referred to in Article 9(1) and on the types of penalties imposed in accordance with Article 11 with the competent authorities of other Member States and with the Commission.

Amendment 177
Pavel Poc

Proposal for a regulation
Article 12 – paragraph 2

Text proposed by the Commission

2. The competent authorities shall exchange information on serious shortcomings detected through checks referred to in Article 9(1) and on the types of penalties imposed in accordance with Article 11 with the competent authorities of other Member States and with the Commission.

Amendment

2. The competent authorities shall exchange information on ***the organization of their checking system for monitoring user compliance with this Regulation and on*** serious shortcomings detected through checks referred to in Article 9(1) and on the types of penalties imposed in accordance with Article 11 with the competent authorities of other Member States and with the Commission.

Justification

In order to ensure a harmonised system of checks across the European Union, and as far as possible with third countries, competent authorities should be engaged in dialogue and cooperation to exchange on best practices regarding the organisation of checks.

Amendment 178
Anna Rosbach

Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission

1. A Union platform on access to genetic resources ***and traditional knowledge associated with genetic resources*** is hereby established.

Amendment

1. A Union platform on access to genetic resources is hereby established.

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 179

Christa Klaß, Herbert Dorfmann, Elisabeth Jeggle, Elisabeth Köstinger

Proposal for a regulation

Article 13 – paragraph 1

Text proposed by the Commission

1. A Union platform on access to genetic resources and traditional knowledge associated with genetic resources is hereby established.

Amendment

1. A Union platform on access to genetic resources and traditional knowledge associated with genetic resources is hereby established. ***Member States which plan to adopt rules governing access to their genetic resources shall first conduct an assessment of the impact of those rules and submit the results to the Union platform for consideration under the procedure laid down in paragraph 5 of this Article.***

Or. de

Amendment 180

Maria do Céu Patrão Neves

Proposal for a regulation

Article 13 – paragraph 1

Text proposed by the Commission

1. A Union platform on access to genetic resources and traditional knowledge associated with genetic resources is hereby established.

Amendment

1. A Union platform on access to genetic resources and traditional knowledge associated with genetic resources is hereby established. ***Member States who envisage adopting access rules as regards their genetic resources shall first conduct an impact assessment of these rules and submit the result of this assessment to the Union platform for consideration,***

pursuant to the procedure laid down in paragraph 5 of this Article.

Or. en

Amendment 181

Christa Klaß, Herbert Dorfmann, Elisabeth Jeggle, Elisabeth Köstinger

Proposal for a regulation

Article 13 – paragraph 2

Text proposed by the Commission

2. The Union platform shall contribute to the streamlining of access conditions at Union level by discussing related issues, including the design and performances of access regimes established in Member States, simplified access for non-commercial research, access practices of collections in the Union, access of Union stakeholders in third countries and the sharing of best practices.

Amendment

2. The Union platform shall contribute to the streamlining of access conditions at Union level by discussing related issues, including the design and performances of access regimes established in Member States, simplified access for non-commercial research, access practices of collections in the Union, access of Union stakeholders in third countries and the sharing of best practices. ***In particular, the platform should advocate that where competent authorities leave requests for access unanswered, the due diligence obligation shall be deemed to have been fulfilled and access shall be granted without any further obligations.***

Or. de

Amendment 182

Maria do Céu Patrão Neves

Proposal for a regulation

Article 13 – paragraph 2

Text proposed by the Commission

2. The Union platform shall contribute to the streamlining of access conditions at Union level by discussing related issues, including the design and performances of

Amendment

2. The Union platform shall contribute to the streamlining of access conditions at Union level by discussing related issues, including the design and performances of

access regimes established in Member States, simplified access for non-commercial research, access practices of collections in the Union, access of Union stakeholders in third countries and the sharing of best practices.

access regimes established in Member States, simplified access for non-commercial research, access practices of collections in the Union, access of Union stakeholders in third countries and the sharing of best practices. ***In particular, the platform should advocate that where competent authorities leave requests for access unanswered, the due diligence obligation shall be deemed to be fulfilled and access should be without any further obligations.***

Or. en

Amendment 183

Cristina Gutiérrez-Cortines, Santiago Fisas Ayxela

Proposal for a regulation

Article 14 – paragraph 1 –point a a (new)

Text proposed by the Commission

Amendment

(aa). Create a catalogue of the available and original genetic resources from each Member State in accordance with Article 7 of the Convention on Biodiversity. The objective will be to have a better knowledge of biodiversity. At the same time they will support third countries in developing a catalogue of their genetic resources with the aim of improving transparency in the access to genetic resources.

Or. en

Justification

Support to third countries can be technical assistance, sharing of knowledge, funds if considered necessary.

Amendment 184
Cristina Gutiérrez-Cortines, Santiago Fisas Ayxela

Proposal for a regulation
Article 14 – paragraph 1 – point a b (new)

Text proposed by the Commission

Amendment

(a)(b) endeavour to ensure, once the fund to be set up under the Convention on Biological Diversity, or any other fund established for the same purpose, has entered into operation, that such funds provide sources of financing for research and the compilation of genetic resource catalogues.

Or. es

Amendment 185
Anna Rosbach

Proposal for a regulation
Article 14 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) support the development and use of cost-effective communication tools and systems in support of monitoring and tracking the use of genetic resources ***and traditional knowledge associated with genetic resources*** by collections and users;

(c) support the development and use of cost-effective communication tools and systems in support of monitoring and tracking the use of genetic resources by collections and users;

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 186
Kriton Arsenis

Proposal for a regulation
Article 16 – paragraph 3

Text proposed by the Commission

3. Every **ten** years after its first report the Commission shall, on the basis of reporting on and experience with the application of this Regulation, review the functioning and effectiveness of this Regulation. In its reporting the Commission shall in particular consider the administrative consequences for public research institutions, small or medium-sized enterprises and micro-enterprises. ***It shall also consider*** the need for further Union action on access to genetic resources and traditional knowledge associated with genetic resources.

Amendment

3. Every **five** years after its first report the Commission shall, on the basis of reporting on and experience with the application of this Regulation, review the functioning and effectiveness of this Regulation. In its reporting the Commission shall in particular consider:

a) the administrative consequences for public research institutions, small or medium-sized enterprises and micro-enterprises;

b) the need to review the implementation of the provisions of this Regulation concerning traditional knowledge associated with genetic resources in light of developments in other relevant international organizations, including, inter alia, the World Intellectual Property Organization, provided that they do not run counter to the objectives of this Regulation, of the Convention on Biological Diversity and the Nagoya Protocol;

*c) the need for further Union action on access to genetic resources and traditional knowledge associated with genetic resources **with the view to implement in full the rights of indigenous and local communities in accordance with Articles 5.2, 6.2, 7 and 12 of the Nagoya Protocol.***

Or. en

Amendment 187
Anna Rosbach

Proposal for a regulation
Article 16 – paragraph 3

Text proposed by the Commission

3. Every ten years after its first report the Commission shall, on the basis of reporting on and experience with the application of this Regulation, review the functioning and effectiveness of this Regulation. In its reporting the Commission shall in particular consider the administrative consequences for public research institutions, small or medium-sized enterprises and micro-enterprises. It shall also consider the need for further Union action on access to genetic resources ***and traditional knowledge associated with genetic resources.***

Amendment

3. Every ten years after its first report the Commission shall, on the basis of reporting on and experience with the application of this Regulation, review the functioning and effectiveness of this Regulation. In its reporting the Commission shall in particular consider the administrative consequences for public research institutions, small or medium-sized enterprises and micro-enterprises. It shall also consider the need for further Union action on access to genetic resources.

Or. en

Justification

Traditional knowledge is a Member State competence and should not be addressed in the Regulation.

Amendment 188
Christa Klaß, Herbert Dorfmann, Elisabeth Jeggle, Elisabeth Köstinger

Proposal for a regulation
Article 16 – paragraph 3

Text proposed by the Commission

3. Every ten years after its first report the Commission shall, on the basis of reporting on and experience with the application of this Regulation, review the functioning and effectiveness of this Regulation. In its reporting the Commission shall in particular consider the administrative

Amendment

3. Every ten years after its first report the Commission shall, on the basis of reporting on and experience with the application of this Regulation, review the functioning and effectiveness of this Regulation. In its reporting the Commission shall in particular consider the administrative

consequences for public research institutions, small or medium-sized enterprises and micro-enterprises. It shall also consider the need for further Union action on access to genetic resources and traditional knowledge associated with genetic resources.

consequences for *specific sectors*, public research institutions, small or medium-sized enterprises and micro-enterprises. It shall also consider the need for further Union action on access to genetic resources and traditional knowledge associated with genetic resources.

Or. de

Amendment 189
Maria do Céu Patrão Neves

Proposal for a regulation
Article 16 – paragraph 3

Text proposed by the Commission

3. Every ten years after its first report the Commission shall, on the basis of reporting on and experience with the application of this Regulation, review the functioning and effectiveness of this Regulation. In its reporting the Commission shall in particular consider the administrative consequences for public research institutions, small or medium-sized enterprises and micro-enterprises. It shall also consider the need for further Union action on access to genetic resources and traditional knowledge associated with genetic resources.

Amendment

3. Every ten years after its first report the Commission shall, on the basis of reporting on and experience with the application of this Regulation, review the functioning and effectiveness of this Regulation. In its reporting the Commission shall in particular consider the administrative consequences for *specific sectors*, public research institutions, small or medium-sized enterprises and micro-enterprises. It shall also consider the need for further Union action on access to genetic resources and traditional knowledge associated with genetic resources.

Or. en

Amendment 190
Pavel Poc

Proposal for a regulation
Article 16 – paragraph 3

Text proposed by the Commission

3. Every ten years after its first report the Commission shall, on the basis of reporting

Amendment

3. Every ten years after its first report the Commission shall, on the basis of reporting

on and experience with the application of this Regulation, review the functioning and effectiveness of this Regulation. In its reporting the Commission shall in particular consider the administrative consequences for public research institutions, small or medium-sized enterprises and micro-enterprises. It shall also consider the need for further Union action on access to genetic resources and traditional knowledge associated with genetic resources.

on and experience with the application of this Regulation, review the functioning and effectiveness of this Regulation. In its reporting the Commission shall in particular consider the administrative consequences for *specific sectors*, public research institutions, small or medium-sized enterprises and micro-enterprises. It shall also consider the need for further Union action on access to genetic resources and traditional knowledge associated with genetic resources.

Or. en

Justification

Since the impact of the regulation may vary from sector to sector depending on the way the different sectors work and develop over time, the Commission should also be required to measure the impacts on specific sectors. Further on, according to Article 8 (c) of the Nagoya Protocol special consideration should be given by Parties to the importance of genetic resources for food and agriculture when implementing the Protocol in their legislation.

Amendment 191 **Gerben-Jan Gerbrandy**

Proposal for a regulation **Article 16 a (new)**

Text proposed by the Commission

Amendment

Article 16 a

Amendment to Directive 2008/99/EC

Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law¹ is hereby amended, with effect from ..., as follows:*

(1) The following point is added to Article 3:

"(j) Illegally acquired genetic resources"

(2) The following indent is added to

Annex A:

"-Regulation (EU) No. .../2013 of the European Parliament and of the Council of ... on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union".

¹ *OJ L 328, 6.12.2008, p. 28.*

** OJ: one year after the date of entry into force of this Regulation.*

Or. en